

**K950475 DISPOSABLE ECG MONITORING ELECTRODE #4530,
#4540**Nov 14, 1995
284 days to decisionK950475 · Product code: **DRX** · Cardiovascular
Source: <https://www.510kdatabase.net/k950475/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Feb 3, 1995
Decision date	Nov 14, 1995
Days to decision	284 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Nikomed U.S.A., Inc.
Location	Belle Mead, NJ, US
Contact	DONALD C EPSTEIN
510(k) history	15 submissions · 15 cleared · 1987-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k950475/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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